

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOVAIL LABORATORIES INTERNATIONAL SRL
a corporation of Barbados,

Plaintiff,

v.

ANDRX PHARMACEUTICALS, LLC and
ANDRX CORPORATION,

Defendants.

C.A. No. 05-730

2005 OCT 14 PM 1:33

COMPLAINT FOR PATENT INFRINGEMENT

For its complaint herein, Plaintiff alleges as follows:

1. Plaintiff Biovail Laboratories International SRL ("Biovail") is a corporation organized and existing under the laws of Barbados and has a place of business in Carolina, Puerto Rico.
2. Upon information and belief, defendant Andrx Pharmaceuticals, LLC ("Andrx LLC") is a limited liability company organized under the laws of Delaware, and maintains a principal place of business at 4955 Orange Drive, Davie, Florida 33314.
3. Upon information and belief, Andrx LLC is a wholly-owned subsidiary of Andrx Corporation ("Andrx Corp."), a corporation organized under the laws of Delaware that maintains a principal place of business at 4955 Orange Drive, Davie, Florida 33314.
4. Upon information and belief, Andrx LLC and Andrx Corp. have common officers and directors; the acts of Andrx LLC complained of herein were done at

the direction of, with the authorization of, and with the cooperation, participation and assistance of Andrx Corp.

5. Andrx LLC and Andrx Corp. are referred to hereinafter collectively as "Andrx."

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States of America and specifically under 35 U.S.C. § 271(e) and jurisdiction exists under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

7. Upon information and belief, Andrx, including through subsidiaries, sells various products and does business throughout the United States including this District, and both Defendants are organized under the laws of Delaware.

8. Upon information and belief, Andrx manufactures bulk pharmaceuticals and pharmaceutical products that are sold and used, including through subsidiaries, throughout the United States, including this District.

CLAIM FOR RELIEF

9. Biovail incorporates paragraphs 1-8 by reference herein.

10. United States Patent No. 5,529,791 (hereinafter "the '791 patent") was lawfully granted on June 25, 1996 to Galephar P.R., Inc., Ltd. ("Galephar"), the assignee of the named inventors, Arthur M. Deboeck and Philippe R. Baudier.

11. A copy of the '791 patent is attached as Exhibit A.

12. Biovail is the exclusive licensee of the '791 patent under a September, 1995 Agreement, which remains in full force and effect, and has the exclusive right to sublicense others and to sue for infringement.

13. Biovail is the holder of New Drug Application ("NDA"), No. 21-392, by which the United States Food & Drug Administration ("FDA") first granted approval for 120, 180, 240, 300, 360 and 420 mg extended release tablets including the active ingredient diltiazem hydrochloride. These tablets are marketed in the United States under the tradename Cardizem[®] LA, and are indicated for the treatment of hypertension, and the management of chronic stable angina.

14. Upon information and belief, Andrx filed in the FDA an Abbreviated New Drug Application ("ANDA") No. 77-686 including a certification with respect to the '791 patent under § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355), seeking approval to market and sell a generic version of Cardizem[®] LA 420 mg tablets prior to the expiration of that patent.

15. Upon information and belief, on or about June 22, 2005, Andrx sent a notice letter to Biovail, Galephar, and to Bank of Nova Scotia in which Andrx represented that it had filed an ANDA for a generic version of Cardizem[®] LA 420 mg tablets, and that it sought approval of its ANDA prior to the expiration of the '791 patent. Biovail received a copy of Andrx's notice letter on or about June 27, 2005.

16. On August 10, 2005, within 45 days of receipt of Andrx's June 22, 2005 notice letter, Biovail brought suit against Andrx in this Court for infringement under 35 U.S.C. § 271(e).

17. Upon information and belief, Andrx filed in the FDA an amendment to ANDA No. 77-686 including a certification with respect to the '791 patent under § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355), seeking approval to market and sell generic versions of Cardizem[®] LA 120, 180, 240, 300, and 360 mg tablets prior to the expiration of that patent.

18. Upon information and belief, on or about August 30, 2005, Andrx sent a notice letter to Biovail, Galephar, and to Bank of Nova Scotia in which Andrx represented that it had filed an amendment to ANDA No. 77-686 for generic versions of Cardizem[®] LA 120, 180, 240, 300, and 360 mg tablets ("Amended ANDA"), and that it sought approval of its Amended ANDA prior to the expiration of the '791 patent. Biovail received a copy of Andrx's notice letter on or about September 2, 2005.

19. Upon information and belief, the Andrx products that are the subjects of its amendment to ANDA No. 77-686 will contain beads that will be compressed with other excipients into tablets. On further information and belief, by virtue of the tableting process, beads of the Andrx products will contain an effective amount of a wetting agent in admixture with one or more diltiazem salts.

20. Because Andrx seeks approval of its Amended ANDA to engage in the commercial manufacture, use or sale of a drug product claimed in the '791 patent before its expiration, Andrx has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A).

21. Biovail is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Andrx's Amended ANDA be a date that is not earlier than the expiration date for the '791 patent,

or any later expiration of exclusivity for the '791 patent to which Biovail is or becomes entitled.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court enter a Judgment that:

a. Andrx infringed one or more claims of the '791 patent by submitting the aforesaid Amended ANDA;

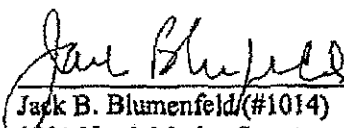
b. A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Andrx, its affiliates and subsidiaries, and their officers, agents, attorneys and employees, and those acting in privity or concert with them, and their successors or assigns, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of compounds claimed in the '791 patent;

c. An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Andrx's Amended ANDA No. 77-686 be a date that is not earlier than the expiration date for the '791 patent, or any later date of exclusivity to which Plaintiff is or becomes entitled;

d. To the extent Andrx has committed any acts with respect to the compounds claimed in the '791 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), Plaintiff be awarded damages for such acts; and

e. For such other and further relief as the Court may deem just and proper under the circumstances.

MORRIS, NICHOLS, ARSHT & TUNNELL



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October 14, 2005

EXHIBIT A



US005529791A

United States Patent [19]

Deboeck et al.

[11] Patent Number: 5,529,791

[45] Date of Patent: Jun. 25, 1996

[54] EXTENDED RELEASE FORM OF
DILTIAZEM

[75] Inventors: Arthur M. Deboeck, Carabo, Puerto
Rico; Philippe R. Bandler, Waterloo,
Belgium

[73] Assignee: Galephar P.R., Inc., Ltd., Carolina,
Puerto Rico

[21] Appl. No.: 311,722

[22] Filed: Sep. 23, 1994

Related U.S. Application Data

[63] Continuation of Ser. No. 68,551, May 28, 1993, abandoned,
which is a continuation of Ser. No. 721,396, Jan. 25, 1991,
Pat. No. 5,284,305.

[51] Int. Cl.⁶ A61K 9/16; A61K 9/58;
A61K 9/62

[52] U.S. Cl. 424/494; 424/490; 424/497;
514/777; 514/785; 514/786; 514/970

[58] Field of Search 424/457, 458,
424/462, 490, 493, 497, 498, 499, 494

[56] References Cited

U.S. PATENT DOCUMENTS

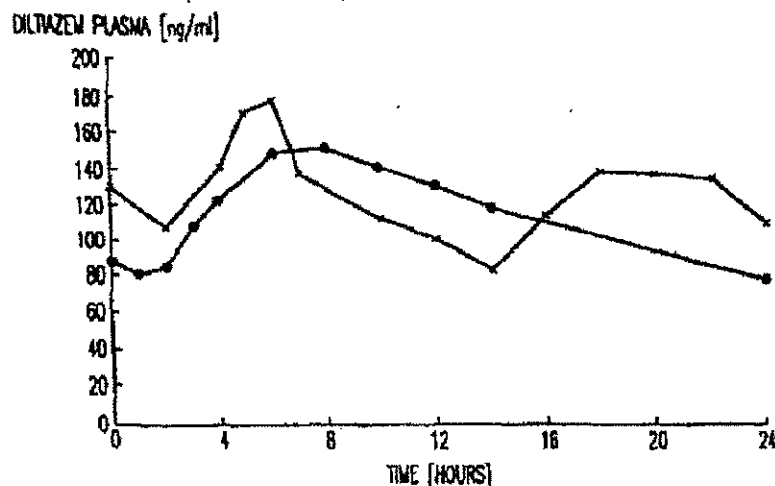
5,112,621 5/1992 Savaris et al. 424/497
5,275,624 1/1994 Carl et al. 424/490

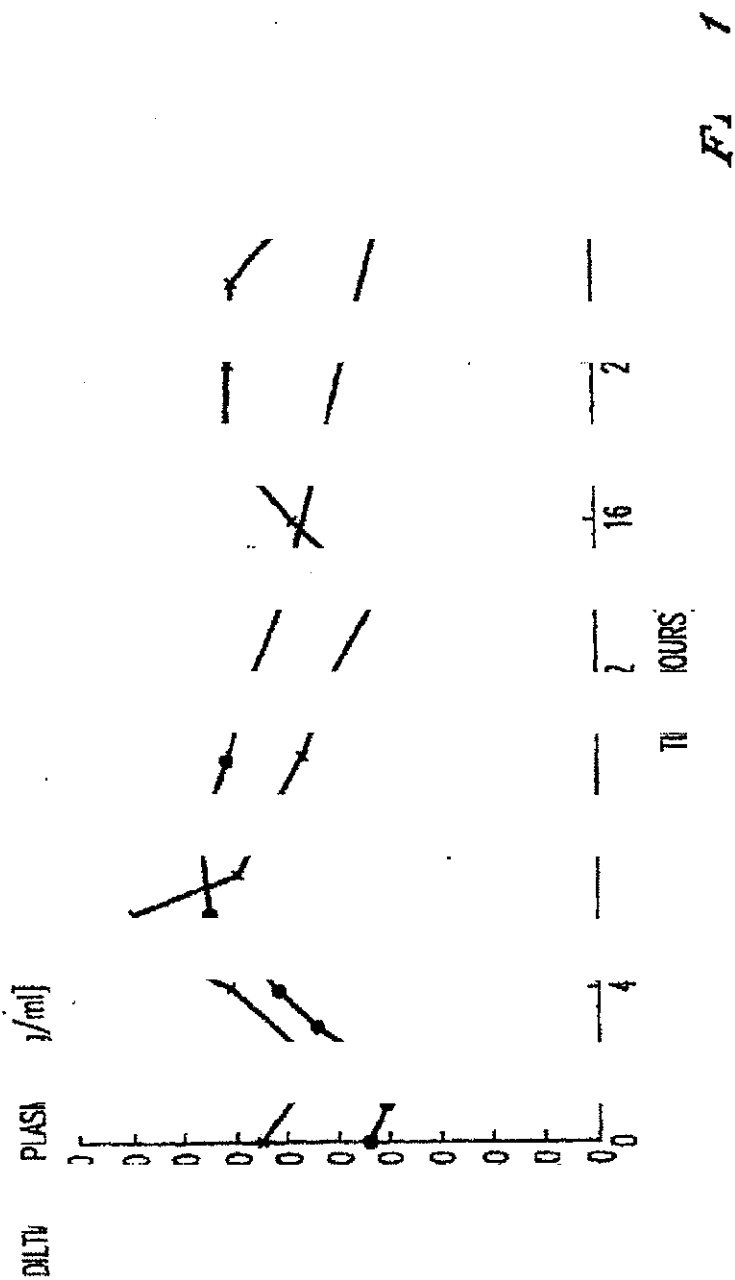
Primary Examiner—Therman K. Page
Assistant Examiner—James M. Spear
Attorney, Agent, or Firm—Obion, Spivak, McClelland,
Maier & Neustadt

[57] ABSTRACT

An extended-release galenical form of Diltiazem or a pharmacologically acceptable salt thereof, which comprises beads containing said Diltiazem or a pharmacologically acceptable salt thereof as an active ingredient and a wetting agent, said beads being coated with a microporous membrane comprising at least a water-soluble or water-dispersible polymer or copolymer and a pharmacologically acceptable adjuvant.

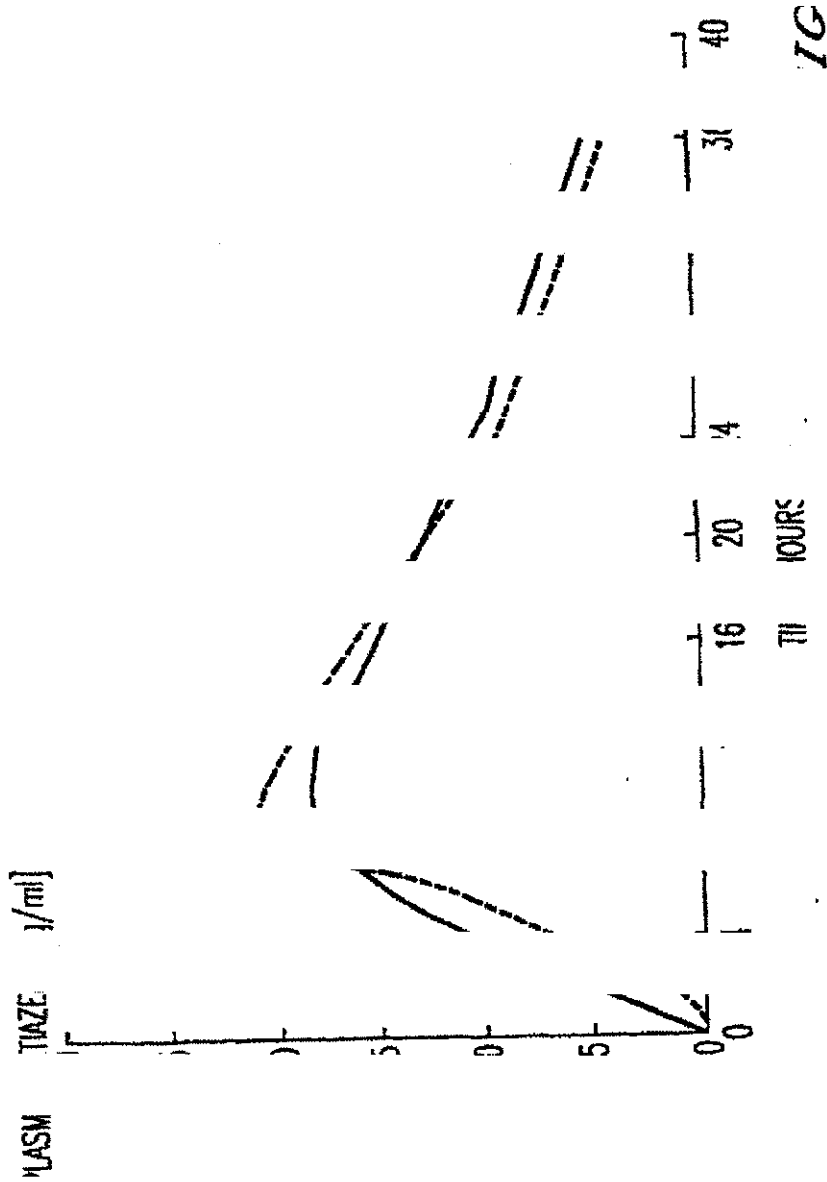
4 Claims, 2 Drawing Sheets





U.S. Patent

JUL 2, 1999



I EXTENDED RELEASE FORM OF DILTIAZEM

is a continuation of application Ser. No. 08/511,000, filed Jun. 26, 1991, now U.S. Pat. No. 5,288,505.

BACKGROUND OF THE INVENTION

of Diltiazem, a process for the manufacture thereof and pharmaceutical compositions containing the same.

1. Description of the Background

which application is now withdrawn in favor of application Ser. No. 08/511,000, filed Jun. 26, 1991, now U.S. Pat. No. 5,288,505.

with which the invention of the present invention is related.

known "slow release" or "extended release" formulations of Diltiazem, which comprise beads containing the pharmaceutically acceptable salt of Diltiazem as an active ingredient and a wetting agent, said beads being

or plasma concentration.

For illnesses which require continuous and constant control, such as hypertension and angina pectoris, Diltiazem

annoying or even impossible to effect, particularly during the night. Further, after each administration of an immediate-release galenic form of Diltiazem, which generally is

organ, more particularly the heart, are alternatively subjected to overdoses and to underdoses of medicine.

In order to alleviate these drawbacks, a first galenic form

Although this form shows a response in peak concentration and in the number of daily intakes from 4 to 2, it does not eliminate high Diltiazem blood concentration between successive administrations. Hence, the method is still flawed

200 layers so as to obtain a core which, thereafter, requires between 20 and 40 layers of coating so as to obtain the membrane. Moreover, the solvent of the polymer solution

flammability and toxicity. Such solvents are also environmentally hazardous. Particular care must be taken to avoid any traces of solvent in the final product because these

Thus, a need continues to exist for a multiple unit extended-release diltiazem hydrochloride galenic form which need be administered only once daily, and from which

SUMMARY OF THE INVENTION

It is also an object of this invention to provide galenic forms of Diltiazem having excellent bioavailability while avoiding plasma concentration peaks.

acceptable salt of Diltiazem, which comprises beads containing the pharmaceutically acceptable salt of Diltiazem as an active ingredient and a wetting agent, said beads being

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates the effect of the present invention in

tional product after the 8th day of administration twice daily.

FIG. 2 illustrates in the solid curve, the mean plasma levels obtained when the product of the present invention is

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Diltiazem or (2S,3S,4S)-1,4-dihydro-2,6-dimethyl-4-methyl-3,4-dihydro-2H-1,4-benzodiazepine-2-thione.

corresponding to U.S. Pat. No. 3,562,257.

The present invention relates to novel galenic forms of Diltiazem being characterized by having an extended-re-

laxem plasma concentrations in a desired, effective range while simplifying the administration of the medicine to only once daily.

a pharmaceutically acceptable salt of Diltiazem as an active substance, associated with at least a wetting agent, the beads being covered with a microporous membrane constituted by

acceptable adjuvant.

In accordance with the present invention, any pharmaceutically acceptable salt of Diltiazem may be prepared in

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In more detail, the microporous membrane whereof the Dilitazem containing microgranules are covered, is constituted by a mixture of a water-soluble and/or water-dispers-

expressed by the percentage of the coating applied to the uncoated beads.

The weight of the microporous membrane may be 2 to

The active substance containing beads are presented in form of spherules the diameter of which is between about 0.05 mm and 2 mm, preferably between about 0.1 mm and

weight. The microporous membrane may contain 5 to 95% and, preferably, 30 to 90% of polymer, polymer mixture or copolymer.

OF BALL INGESTION ON THE COLEMAN, THE FOLLOWING MEMBRANES MAY MORE PARTICULARLY BE OBTAINED:

saccharose, mannitol, sorbitol;

such as the hydrochloride, and at least a wetting agent, coated with at least one polymer-based microporous membrane, the coated beads being contained in capsules, pills

under the name of macroesters (Clatofase, France) or under the name of crodesters (Croda, U.K.);

or less extent or suitable

extended-release in the gastro-intestinal tract, said process entailing preparing beads and coating the same with a single microporous membrane.

and xanthines, caffeine, KAVA;

sorbitol fatty acid esters (Span, Atlas, U.S.A.);

polyglycides-glycolides and polyglycides-alcohols esters

wetting agent(s) in a mixture or slurry in water, or in solution, in the presence of a solvent, such as water, so as to obtain an extrudable paste or plastic mass. Said paste is extruded into an extruder and then reformed either

Microcrystalline celluloses, such as Avicel products (PMC, U.S.A.); methylcelluloses, carboxymethylcelluloses, hydroxyethylcelluloses (Natrucel, Hercules, U.S.A.);

microspheres or beads from the extruded product provided in the form of spaghetti, an apparatus called "spheronizer" (ATVVA (Société Belge) or MARIMIZER (SPHILU

polymer or copolymer constituting the microporous membrane, may be mentioned particularly polyacrylates and polymethacrylates of the Eudragit type, such as Eudragit

agglomeration of the Dilitazem or salt thereof, such as the chlorhydrate, contingently mixed to at least a wetting agent with a dispersion or solution of at least one wetting

hydroxypropylmethylcellulose and their derivations.

These polymers or copolymers may be associated into the microporous membrane with at least one adjuvant as exam-

plary granulator such as the collette (Belgium) type.

The obtained beads are dried by any means, for example in an oven or by means of a gas in a fluidized bed.

polypropylene glycols and polyvinylpyrrolidones; pigments, such as iron oxides and titanium oxide; others such as lactose and mannitol;

means of any one of the above described techniques, may contain the following weight proportions of the Dilitazem or salt thereof, wetting agents and carriers or excipients:

derived from sorbitol possibly containing polyoxyethylene chains, preferably surfactive agents of the Tween type, notably Tween 80 as well as polyoxyethylene/oxidin;

PMCL, U.S.A.); 2 to 10% Methocel E 5 (hydroxypropylmethylcellulose of DOW, U.S.A.);

in addition to the polymer or copolymer, the microporous membrane contains, preferably, talc and/or magnesium stearate as a lubricant, polyvinylpyrrolidone as a plasticizing

least one of the above-named polymers and at least one of the above-mentioned adjuvants onto said beads. This pul-

verization may be carried out by spray-gunning or by pulverizing the above-named dispersion into a turbine or fluidized bed.

comprised between 0.7 mm and 1.4 mm are retained, 1,179 g of beads were obtained yield (84%).

in general, from about 120 mg to about 480 mg per day of Diltiazem salt is administered per day per patient in total. Additionally, the extended release form composition of

Crystalline P 160	39.5 g
Microcrystalline cellulose (Avicel pH 101)	70 g
Povidone K 30	10.5 g

with the Diltiazem salt.

For example, other pharmaceutically active ingredients, such as β -adrenoceptor blocking agents or diuretics may be

ml water USP is added and the mixing is pursued during 10 minutes more until a plastic mass is obtained. This mass is then extruded through a Pulli Pandel extruder equipped with

such as Propranolol, Atenolol, Lisinopril, Furosemide or Solisalol may be used, for example.

As examples of diuretic agents, drugs such as Hydrochlorothiazide, Furosemide, Ethacrynic Acid or Ethacrynic Acid.

at 60° C, the beads are sieved so as to eliminate the ones with a size larger than 1.4 mm and with a size smaller than 0.7 mm. The amount of beads obtained with size comprised

not be.

The present invention will now be further illustrated by reference to certain examples, which are provided solely for

Beads prepared in Example 1 were coated in a STREA-1 (Acromatic) fluidized bed using the "Top spraying" technic.

starting form an aqueous dispersion which contains by weight:

10 to 70 Eudragit E30D (polymer)

Coating suspension composition:

Magnesium stearate	12.5 g
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0.5 to 15% polyvinylpyrrolidone (plasticizing agent);
0.01 to 2% silicone oil (antifoaming agent);
0.05 to 5% polysorbate 80 (wetting agent)

water	100.0 g
Silicofloc	1.0 g
Tween 80	0.8 g

EXAMPLES

The present invention will now be further illustrated by reference to certain examples, which are provided solely for

ml dissolution medium consisted of a phosphate buffer pH 5.8 and the revolution speed 100 rpm.

paring the same, therapeutic applications thereof and pharmacokinetic controls using the present galenic forms.

1	62
12	84

Diltiazem hydrochloride	1120 g
Lactose	139 g
Microcrystalline cellulose (Avicel pH 101)	140 g
Povidone K 30	21 g

1 kg of beads as in Example 1 were obtained using a fluidized bed coater equipped with a "waster" system. 8 kg of uncoated beads were introduced in an Automatic Acroposter and 4 kg of the Eudragit coating suspension was applied

granulating same though the obtained plastic mass is extruded through a cylinder with 1 mm diameter holes (Alexanderwerk). The small cylinders are rounded, so as to

Coating suspension:

Magnesium stearate	0.636 kg
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8

hydroxypropylmethylcellulose
Polyethylene glycol 400
Simethicone emulsion
Eudragit NE 30 D

300 mg
0.007 kg
0.018 kg
12.4 kg

Cardizen SR® after a twice daily administration.

Fourth, the time during the concentration is above 75% of the maximum concentration is 46% longer after the once

The results were obtained using the same equipment as in Example 3. The dissolution medium was composed of 900 ml of water and the temperature was maintained of $37 \pm 0.5^\circ$

The product of Example 4 was given to 24 healthy volunteers and the bioavailability was measured after single oral dose of 300 mg given with and without food.

elapsed time [h]	percent dissolved [%]
2	9
4	33

experiment was repeated in the same subjects with the other treatment at an interval of 7 days. The plasma concentration of Diltiazem was determined in all available samples using

Pharmacokinetic results

The new galenic form of Example 4 was the object of a pharmacokinetic study in comparison with a form in

market and assessment of bioequivalence. FIG. 2 curves shows the mean plasma levels obtained when the product is taken without food and the dotted curve the mean plasma

the 2 products. The product of Example 4 was administered at a dose of 300 mg once daily while the product on the market was administered twice daily at a dose of 150 mg

Pharmacokinetic parameters - product of Example 4

	Fasting	Random	Food
Mean residence time	h	0.243 ± 0.034	0.300 ± 0.027
K_e	h ⁻¹	100 ± 4.8	112 ± 5.9
Maximum	mg/ml		

withdrawn after the Cardizen SR® administration. Diltiazem plasma levels were assayed using a specific high pressure liquid chromatographic method. FIG. 3 shows the

SR®.

FIG. 1

Area under the curve [0-24 h]	mg·h/ml	2782 ± 107	2864 ± 122
Maximum	mg/ml	116.3 ± 34.1	191.7 ± 85.3

Time during the concentration is above 75% of the maximum	A	3.8 ± 2.3	6.7 ± 3.7
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Example 4 given with food is bioequivalent to the administration without food to within less than 20% regarding area under the curve, mean residence time and maximum con-

From all the results it appears clearly that the product of the present invention can be administered once a day and that the plasma concentration variations are lower than the

apparent to one skilled in the art that many changes and modifications may be made to the above-described embodiments while remaining within the spirit and the scope of the

1. AND BIOEQUIVALENT COMPARISON OF THE TWO

First, FIG. 1 shows that the Diltiazem plasma levels obtained after a once daily administration of one of the

more pharmaceutically-acceptable salts of Diltiazem which comprises beads containing an effective amount of one or

Second, the bioavailability, expressed by the area under the curve of the 2 products, is equivalent (no statistical detectable difference).

Diltiazem in each bead, ensuring that the solubility of the Diltiazem is unaffected by the pH of the gastrointestinal tract

or other adverse conditions which the composition will meet therein, said beads being coated with a microporous membrane comprising at least a water-soluble or water-dispers-

2. The composition of claim 1, wherein the wetting agent is a sugar.

3. The composition of claim 1, wherein the effective

and wherein the wetting agent is selected from the group consisting of sugars, C₁₂-C₂₀ fatty acid esters of sucrose or glucose, derivatives of sucrose, fatty acid

4. The composition of claim 1, wherein the wetting agent is sucrose stearate, the water-soluble or water-dispersible polymer or copolymer is hydroxypropylmethyl-cellulose

ide-polyglycidide, lecithins and a combination thereof.

* * * * *

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOVAIL LABORATORIES INTERNATIONAL SRL
a corporation of Barbados,

Plaintiff,

v.

ANDRX PHARMACEUTICALS, LLC and
ANDRX CORPORATION,

Defendants.


C.A. No. 1:05-cv-00586-30

2005 OCT 14 PM 3:31

PLAINTIFF'S RULE 7.1. DISCLOSURE STATEMENT

Pursuant to Fed. R. Civ. P. 7.1(a), the undersigned counsel for Biovail Laboratories International SRL, which is a non-governmental corporate party, certifies that Biovail Laboratories International SRL is a wholly-owned subsidiary of Biovail Corporation and there is no publicly held corporation that owns 10% or more of the stock of Biovail Corporation.

MORRIS, NICHOLS, ARSHT & TUNNELL



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October 14, 2005

SAO 85 (Rev 8/98) Notice, Consent, and Order of Reference — Exercise of Jurisdiction by a United States Magistrate Judge

UNITED STATES DISTRICT COURT

District of _____

Plaintiff
V.

NOTICE, CONSENT, AND ORDER OF REFERENCE —
EXERCISE OF JURISDICTION BY A UNITED STATES
MAGISTRATE JUDGE

Case Number:

C 5 - 7 3 0 -

Defendant

NOTICE OF AVAILABILITY OF A UNITED STATES MAGISTRATE JUDGE TO EXERCISE JURISDICTION

In accordance with the provisions of 28 U.S.C. §636(c), and Fed.R.Civ.P. 73, you are notified that a United States magistrate judge of this district court is available to conduct any or all proceedings in this case including a jury or nonjury trial, and to order the entry of a final judgment. Exercise of this jurisdiction by a magistrate judge is, however, permitted only if all parties voluntarily consent.

You may, without adverse substantive consequences, withhold your consent, but this will prevent the court's jurisdiction from being exercised by a magistrate judge. If any party withholds consent, the identity of the parties consenting or withholding consent will not be communicated to any magistrate judge or to the district judge to whom the case has been assigned.

An appeal from a judgment entered by a magistrate judge shall be taken directly to the United States court of appeals for this judicial circuit in the same manner as an appeal from any other judgment of this district court.

CONSENT TO THE EXERCISE OF JURISDICTION BY A UNITED STATES MAGISTRATE JUDGE

In accordance with provisions of 28 U.S.C. §636(c) and Fed.R.Civ.P. 73, the parties in this case consent to have a United States magistrate judge conduct any and all proceedings in this case, including the trial, order the entry of a final judgment, and conduct all post-judgment proceedings.

Party Represented	Signatures	Date
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

ORDER OF REFERENCE

IT IS ORDERED that this case be referred to _____
United States Magistrate Judge, to conduct all proceedings and order the entry of judgment in accordance with 28 U.S.C. §636(c) and Fed.R.Civ.P. 73.

Date

United States District Judge

**NOTE: RETURN THIS FORM TO THE CLERK OF THE COURT ONLY IF ALL PARTIES HAVE CONSENTED
ON THIS FORM TO THE EXERCISE OF JURISDICTION BY A UNITED STATES MAGISTRATE JUDGE.**



CORPORATION SERVICE COMPANY

Notice of Service of Process

CXT / ALL
Transmittal Number: 4206236
Date Processed: 10/18/2005

Primary Contact: Rob Goldfarb Esq.
Andrx Corporation
8151 Peters Road
Floor 4th
Plantation, FL 33324

Copy of transmittal only sent to: Ms. Karina de Windt

Entity:	Andrx Corporation Entity ID Number 1980756
Entity Served:	Andrx Corporation
Title of Action:	Biovail Laboratories International SRL vs. Andrx Pharmaceuticals, LLC
Document(s) Type:	Summons/Complaint
Nature of Action:	Trademark / Copyright / Patent
Court:	United States District Court , Delaware
Case Number:	05-730
Jurisdiction Served:	Delaware
Date Served on CSC:	10/18/2005
Answer or Appearance Due:	20 Days
Originally Served On:	CSC
How Served:	Personal Service
Plaintiff's Attorney:	Jack B. Blumenfeld 302-658-9200

Information contained on this transmittal form is for record keeping, notification and forwarding the attached document(s). It does not constitute a legal opinion. The recipient is responsible for interpreting the documents and taking appropriate action.

To avoid potential delay, please do not send your response to CSC
2711 Centerville Road Wilmington, DE 19808 (888) 690-2882 | sop@cscinfo.com

AO 440 (Rev. 10/93) Summons in a Civil Action

United States District Court

DISTRICT OF DELAWARE

BIOVAIL LABORATORIES INTERNATIONAL SRL

SUMMONS IN A CIVIL ACTION

Plaintiff,

v.

ANDRX PHARMACEUTICALS, LLC, and
ANDRX CORPORATION,

CASE NUMBER: 1:05-cv-00586-GMS

Defendants.

TO: Andrx Corporation
c/o Corporation Service Company
2711 Centerville Road
Suite 400
Wilmington, DE 19808

YOU ARE HEREBY SUMMONED and required to file with the Clerk of this Court and serve upon

PLAINTIFF'S ATTORNEY:

Jack B. Blumenfeld, Esquire
Morris, Nichols, Arsh & Tunnell
1201 N. Market Street, P.O. Box 1347
Wilmington, DE 19899-1347

an answer to the complaint which is herewith served upon you, within twenty (20) days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You must also file your answer with the Clerk of this Court within a reasonable period of time after service.

PETER T. DALLEO

CLERK

DATE

10-14-05

BY DEPUTY CLERK

AO 440 (REV. 10/93) Summons in a Civil Action

RETURN OF SERVICEService of the Summons and amended complaint was made by me¹

DATE

NAME OF SERVER (PRINT)

TITLE

Check one box below to indicate appropriate method of service

☐ Served personally upon the defendant. Place where served: _____☐ Left copies thereof at the defendant's dwelling house or usual place of abode with person of suitable age and direction then residing therein.

Name of person with whom the summons and complaint were left: _____

☐ Returned unexecuted: _____☐ Other (specify): _____**STATEMENT OF SERVICE FEES**

TRAVEL

SERVICES

TOTAL

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Return of Service and Statement of Service Fees is true and correct.

Executed on _____

Date

Signature of Server

Address of Server

1) As to who may serve a summons see Rule 4 of the Federal Rules of Civil Procedure